UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ABBOTT LABORATORIES, ABBOTT DIABETES CARE INC., and ABBOTT DIABETES CARE SALES CORPORATION,	:	15 Civ. 05826 (CBA) (MDG)
Plaintiffs,	:	
-against-	:	
ADELPHIA SUPPLY USA, ET AL.,	:	
Defendants	:	

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO ONLINE DEFENDANTS' MOTION TO DISMISS

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Abbott Laboratories, Abbott Diabetes Care, Inc., and Abbott Diabetes Care Sales Corp. (collectively, "Abbott") submit this opposition to the motion to dismiss filed by Defendants MISAR LLC, Leslie Boeshart, NWHOLESALEDEALS, Inc., Gregory Sargent, and Hsiu Sargent (collectively, the "Online Defendants").

INTRODUCTION

Of the three hundred defendants named in the Second Amended Complaint ("Complaint" or "SAC"), these five Online Defendants are the only ones that have challenged the plausibility of Abbott's claims of trademark infringement. None of the other defendants have moved on these grounds. And for good reason: the Court already entered a preliminary injunction against all of the defendants, including the Online Defendants, based on Abbott's well-pled claims of trademark infringement.

While the Online Defendants label their motion as one to dismiss under Rule 12(b)(6), in reality they are seeking both reconsideration of the Court's preliminary injunction and summary judgment. *See, e.g.*, Defs. Br. at 18, 24. First, the Online Defendants seek to overturn the Court's holding that *Original Appalachian* controls here. The law-of-the-case doctrine precludes that argument, and any right the defendants had to challenge the applicability of *Original Appalachian* has long been abandoned. Second, the Online Defendants seek to introduce extrinsic evidence that is neither part of the Complaint nor incorporated by reference. Third, the extrinsic evidence the Online Defendants proffer creates at best a factual dispute that cannot be resolved at this stage.

Original Appalachian applies here. As this Court and others have consistently found, while consumer confusion is typically measured by the *Polaroid* factors, these factors are inapplicable in the case of "gray" goods. This is because the *Polaroid* test presumes the

existence of two entities using two similar, but not identical, marks. Where the goods in question bear the same mark, Lanham Act liability arises where they are not intended for domestic sale and are materially different from the domestic version. Here, the Complaint alleges that the international FreeStyle® and FreeStyle Lite® (together, "FreeStyle") test strips are not cleared for sale in the United States and that Abbott does not sell or allow for the sale of international FreeStyle test strips in the United States. And by the Online Defendants' own admission, "the complaint ably sets forth allegations establishing a difference in domestic and international packaging." These differences are as numerous as they are material. In granting preliminary relief, this Court not only found that Abbott had adequately alleged Lanham Act liability based on these allegations, but that Abbott was likely to succeed on the same.

To avoid these findings, the Online Defendants submit copies of some of their eBay and Amazon sales listings and customer feedback. The Online Defendants do not submit this "evidence" simply for the Court to take notice of its contents. Instead, they rely on it to draw a series of baseless inferences and conclusions about the nature of their customers and the extent to which they can be confused by the differences between U.S. and international strips. The Online Defendants claim that all of their customers are end-users who know exactly what they are getting. This argument fails instantly as the Online Defendants' customers are not all end-users. As alleged in the Complaint, they sold to Abbott. Moreover, documents produced *by the Online Defendants themselves* show that they sold to other gray market distributors.

Even if the Online Defendants' customers were all end-users, the Complaint alleges that the differences between the domestic and international strips would be material to all consumers, regardless of whether they bought from a brick-and-mortar pharmacy or an online vendor. There is no basis to conclude from the mere fact that a consumer buys online that the differences would

not be material to that person. Nor is there any basis to conclude as a matter of law that the use of the term "Product May Vary" would in any way warn consumers of all the differences or mitigate the significant confusion caused by those differences.

Finally, the Online Defendants dispute that the sale of international test strips undermines Abbott's ability to control the quality of its product. While the Complaint plainly alleges the need for targeted, country-specific recalls and the adverse impact diversion can have on such recalls, the Online Defendants' response is simply that "there is no reason to believe that." However, the question is not what the Online Defendants want to believe, or even what Abbott can prove at trial; it is whether Abbott has plausibly alleged that the diversion of international test strips interferes with Abbott's recall processes. Abbott has alleged and the Court has found that "the domestic sale of international test strips thwarts Abbott's legitimate quality-control measures."

BACKGROUND

The substance of Abbott's claims and procedural history of this case has already been recounted to the Court numerous times. *See, e.g.* Plaintiffs' Omnibus Mem. of Law in Opp'n to Defs. Mot. to Dismiss, D.E. # 675. Abbott limits its discussions in this brief to the relevant allegations in the Complaint regarding the Online Defendants' trademark violations.

A. The Packaging and Instructions for FreeStyle Test Strips Differ Dramatically Between the United States and the Rest of the World

Abbott makes and sells the FreeStyle brand of blood glucose test strips, which millions of individuals with diabetes use on a daily basis to monitor their blood sugar and help them control their disease. SAC ¶¶ 2, 21-23, 340-43. Abbott manufactures and sells FreeStyle-brand test strips worldwide. *Id.* ¶¶ 349-52, 375.

Public health agencies in the United States and abroad regulate the sale of test strips and what must be included and excluded from their labels and packaging. SAC ¶¶ 11-13, 354. In the United States, the U.S. Food and Drug Administration ("FDA") has cleared the distribution and use of FreeStyle test strips under very specific, stringent package labeling and usage requirements. *Id.* International regulatory agencies also have very particular, but different, regulatory requirements. *Id.* As a result, FreeStyle test strips packaged for sale outside the United States have different labels and instructions than U.S. FreeStyle test strips, and therefore are not cleared by the FDA for domestic distribution. *Id.*

While the international and domestic FreeStyle test strips themselves are the same, their packaging and instructions differ in the following material ways:

- **NDC Number**: Every retail box of U.S. FreeStyle test strips has a National Drug Code ("NDC") number, which is a ten-digit number that incorporates Abbott's assigned product and package codes. Abbott uses the NDC number to track U.S. retail sales and to ensure the test strips are appropriate for reimbursements and rebates. The NDC number appears both on the front and bottom of U.S. boxes. International FreeStyle boxes do not have an NDC number.

- **Toll-Free Number**: Every box of U.S. FreeStyle test strips provides a U.S. toll-free phone number for consumers to call with any inquiries, complaints, or issues. Abbott's call center for U.S. consumers plays a vital role in receiving these calls and providing important instructions about how to properly test their blood glucose levels and information related to quality issues and recalls. International FreeStyle boxes do not provide the U.S. toll-free number and instead have international numbers that are not generally accessible from the United States.

- **Test Sites**: When performing a blood glucose test, the patient must obtain a blood drop from a "test site" on his or her body. Many patients test their glucose levels multiple times per day and would like to be able to use a number of different test sites. U.S. and international FreeStyle test strips feature different approved test sites. U.S. FreeStyle test strips are cleared by the FDA for testing at only three sites: finger; upper arm; and palm. International FreeStyle test strips are approved for testing at seven sites: finger; upper arm; palm; *and* back of hand; forearm; calf; thigh. Any international FreeStyle test strips that are diverted to and distributed in the United States would indicate testing sites that are not cleared by—and were *explicitly rejected by*—the FDA in the United States.

- **Languages**: Every box of test strips contains an instructional insert, which in addition to the outer packaging provides a substantial amount of vital information, including directions and warnings concerning the use of FreeStyle test strips. U.S. FreeStyle test strip instructions are written in English and Spanish. Several international FreeStyle test strip boxes do not include English or Spanish instructions; others include additional, potentially confusing foreign languages.

- **Units of Measurement**: The FDA requires that U.S. products use specific units of measurement, including milligrams and deciliters. Handling and use instructions for international FreeStyle test strips utilize units of measurement that are not permitted by the FDA because they can confuse U.S. consumers.

- **Temperature**: The outer package labeling for U.S. and international FreeStyle test strips state the range of temperatures in which they can be safely stored. However, temperatures on the outside product packaging for international FreeStyle test strips are displayed in degrees Centigrade, while the outside product packaging for U.S. FreeStyle test strips display degrees in Fahrenheit and Centigrade, as required by the FDA.

- **Symbols**: International FreeStyle test strips are packaged in boxes and with instructions that bear various symbols concerning, among other things, the manufacturer, expiration date, and storage temperature limitations. These symbols are not present on U.S. FreeStyle test strip packaging and are prohibited by the FDA.

- **Written Warnings**: The outer package label of U.S. FreeStyle test strips provides several FDA-required written warnings and instructions, including "Do no reuse" and "For *in vitro* diagnostic use." The outer package label of international FreeStyle test strips does not provide these written warnings.

SAC ¶¶ 12-13, 353-67. These material differences render diverted international FreeStyle test strips misbranded and confusing to all consumers. SAC ¶¶ 13, 15, 385-86.

B. The Sale of International FreeStyle Test Strips in the United States Undermines Abbott's Quality Control Measures

FreeStyle test strips are manufactured in Ireland with a specific stock keeping unit ("SKU") and lot number. SAC ¶ 375. Each lot is only manufactured for sale in a specific country. *Id.* Abbott uses the SKU and lot number to track where the strips are shipped and then to monitor them should any safety or quality issues arise. SAC ¶ 376.

Abbott devotes a substantial amount of effort and resources to ensure product quality and consumer safety. SAC ¶ 379. Diverted FreeStyle test strips seriously undermine Abbott's

product quality and present a threat to patient health. SAC ¶¶ 15, 386. When a recall is warranted, recall notices are only sent to the countries where the recalled product was authorized for sale. SAC ¶ 378. Abbott informs them of the affected SKU and lot number, the issue, and any further action that may be necessary. SAC ¶ 377. Abbott is unable to track international FreeStyle test strips that are diverted into the United States. American consumers of diverted test strips may not receive notice of a recall affecting that lot of test strips; or Abbott may not be able to identify the consumer and provide that person with any information that may affect the usage, efficacy, or safety of the test strips. SAC ¶¶ 375-78. Thus, the diversion of these test strips undermines Abbott's ability to disseminate important information about particular lot numbers and ensure that recall efforts are complete. *Id.*

C. The Online Defendants Sold Diverted International FreeStyle Test Strips in the United States

MISAR LLC is a Washington-based company that sells international FreeStyle test strips in the United States on Amazon.com under the username MISAR LLC. SAC ¶ 202. Leslie Boeshart is the owner of MISAR LLC, and in that capacity exercises control over MISAR LLC and was a moving, conscious, active force behind MISAR LLC's infringement. SAC ¶ 204. On January 12, 2016, MISAR LLC and Leslie Boeshart (collectively, "MISAR") sold a box of diverted international FreeStyle test strips to Abbott. SAC ¶ 493. All of the material differences identified above were present in this box's packaging and instructions. *Id.*

NWHOLESALEDEALS, Inc. is a Washington-based company that sells international FreeStyle test strips in the United States on Amazon.com under the username nwholesaledeals. SAC ¶ 190. Hsiu Sargent is the owner of NWHOLESALEDEALS, Inc., and in that capacity exercises control over NWHOLESALEDEALS, Inc. and was a moving, conscious, active force behind NWHOLESALEDEALS, Inc.'s infringement. SAC ¶ 191. On January 15, 2016,

NWHOLESALEDEALS, Inc. and Hsiu Sargent (collectively, "NWHOLESALEDEALS") sold a box of diverted international FreeStyle test strips to Abbott. SAC ¶ 487. All of the material differences identified above were present in this box's packaging and instructions. *Id.*

Gregory Sargent is a Washington resident who sells international FreeStyle test strips in the United States on eBay under the username ghs-corp. SAC ¶ 189. On January 15, 2016, Gregory Sargent sold a box of diverted international FreeStyle test strips to Abbott. SAC ¶ 486. All of the material differences identified above were present in this box's packaging and instructions. *Id.*

The Online Defendants advertised to consumers and the marketplace their ability and willingness to sell FreeStyle test strips. SAC ¶ 385. These advertisements and the Online Defendants' subsequent sales of international FreeStyle test strips were made through, among other things, websites and emails. SAC ¶ 385. But when the Online Defendants' customers received these diverted international FreeStyle test strips, which bear certain of Abbott's trademarks but which are materially different from what U.S. consumers expect, they were likely confused and disappointed. SAC ¶¶ 10, 15, 386.

D. The Court's Temporary Restraining Orders and Preliminary Injunctions

Abbott initiated this litigation on October 9, 2015, filing a complaint and moving for a temporary restraining order ("TRO") and preliminary injunction against 48 defendants. In granting the TRO, United States District Judge Dora L. Irizarry found that Abbott had "amply demonstrated . . . a likelihood of success on the merits of their claims." D.E. # 21 at 4. After limited expedited discovery and a two-day evidentiary hearing, this Court granted Abbott's request for a preliminary injunction, findings that Abbott "made clear showings that it is likely to

succeed on the merits under both the materially-different and the quality-control standards." D.E. # 131 at 15.

On November 20, Abbott amended its complaint, naming and seeking a TRO and preliminary injunction against 54 additional defendants. After granting Abbott's second request for a TRO and holding another contested hearing, the Court issued a preliminary injunction against the newly-added defendants, again finding that "it is clear that these strips satisfy the low threshold of materiality that separates genuine from non-genuine gray goods." D.E. # 258 at 3; *see also id* at 10-11. The Court also found that "Abbott has in place legitimate quality-control measures that will be inhibited by the domestic sale of international test strips." *Id.* at 11.

On March 28, 2016, Abbott filed a second amended complaint, naming and seeking a TRO and preliminary injunction against 206 additional defendants—including MISAR, NWHOLESALEDEALS, and Gregory Sargent. As none of the new defendants opposed it, *including the Online Defendants*, the Court granted the preliminary injunction, stating "[a]s the Court has already twice found, Abbott is likely to succeed on the merits of its trademark-infringement claims because the differences between international and domestic FreeStyle test strips are material and the gray marketing of those strips interferes with Abbott's quality-control measures." D.E. # 423 at 3.

Two defendants, H&H Wholesale and Matrix Distributors, appealed the Court's preliminary injunction order. Following oral argument on October 27, 2016, the Second Circuit summarily denied that appeal in less than one week, finding the Court's order "thorough and well-reasoned." *See* Case No. 15-3785, D.E. # 92-1 (2d Cir. Nov. 3, 2016).

ARGUMENT

I. STANDARD OF REVIEW

A Rule 12(b)(6) motion to dismiss must be denied if the complaint states "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Plausibility," however, does not mean "probability." *Id.* "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* All facts must be construed in the light most favorable to the nonmoving party. *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974).

While the Court may consider a written instrument, such as a contract or prospectus, "attached to the complaint as an exhibit or incorporated in the complaint by reference," *Subaru Distribs. Corp. v. Subaru of Am., Inc.*, 425 F.3d 119, 122 (2d Cir. 2015), it is not appropriate to consider "affidavits, depositions or other extraneous documents not set forth in the complaint," *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47 (2d Cir. 1991). Any ambiguities in any such written instruments must be resolved in the nonmovant's favor. *See Int'l Audiotext Network v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995).

II. THE COMPLAINT STATES PLAUSIBLE CLAIMS FOR TRADEMARK INFRINGEMENT

To prevail on its trademark infringement claim, Abbott must show that it has legally protectable trademarks and that the Online Defendants' use of the trademarks is causing a likelihood of confusion among customers. *PepsiCo, Inc. v. F & H Kosher Supermarket, Inc.*, 2011 U.S. Dist. LEXIS 143331 (E.D.N.Y. Aug. 26, 2011), *adopted by* 2011 U.S. Dist. LEXIS 142430 (E.D.N.Y. Dec. 12, 2011). There is no question that Abbott's trademarks merit protection (*see* SAC ¶¶ 344-352), and the Online Defendants do not contend otherwise. Rather,

notwithstanding this Court's findings to the contrary, the Online Defendants contend that their sale of international FreeStyle strips in the United States is not likely to cause consumer confusion.

As Abbott made clear in its preliminary injunction briefing, and as the Court consistently found in granting three consecutive preliminary injunctions, the multi-factor test articulated in *Polaroid Corp. v. Polarad Elec. Corp.*, 287 F.2d 492 (2d Cir. 1961), does not apply here. *See* D.E. # 131 at 8-9; D.E. # 258 at 5-6; *see also Novartis Animal Health US, Inc. v. Abbeyvet Export Ltd.*, 409 F. Supp. 2d 264, 266 (S.D.N.Y. 2005) (finding the *Polaroid* test "not useful in the context of gray market goods, since such goods typically utilize the exact same marks, sold in the original packaging legitimately obtained from the manufacturer"); *Prince of Peace Enters. v. Top Quality Food Market, LLC*, 2007 U.S. Dist. LEXIS 16391, at *12 (S.D.N.Y. Mar. 7, 2007) (same); *see also Original Appalachian Artworks, Inc. v. Granada Electronics, Inc.*, 816 F.2d 68, 74 (2d Cir. 1987) (Cardamone, J., concurring) (stating that the traditional consumer confusion test is "difficult to apply" in gray good cases).

A different standard applies in gray goods cases like this. As this Court has explained, the sale of gray goods gives rise to Lanham Act liability in two instances: "[f]irst, goods that are not intended for domestic sale and are materially different from domestic goods"; or "[s]econd, goods sold in contravention of legitimate, established, substantial, and nonpretextual quality-control measures that the trademark holder follows, the sale of which will diminish the value of the mark." D.E. # 131 at 9 (citing *Original Appalachian*, 816 F.2d at 73 and *Warner-Lambert Co. v. Northside Dev. Corp.*, 86 F.3d 3, 6 (2d Cir. 1996)). Each of these tests serves as a proxy "for the fundamental question under the Lanham Act: whether consumer confusion is likely."

Id. (citing *Nitro Leisure Prods., L.L.C. v. Acushnet Co.*, 341 F.3d 1356, 1362 (Fed. Cir. 2003). Both tests apply equally here, and both require the same result: denial of Defendants' motion.

A. International FreeStyle Test Strips Are Not Intended For Sale in the United States and Are Materially Different

The Online Defendants do not dispute that the differences between U.S. and international FreeStyle test strips are material to the average consumer. *See* Defs. Br. at 2. Instead, they argue that *Original Appalachian* does not apply here, and even if it did, those differences would not be material to the Defendants' online customers. The Online Defendants are wrong on both fronts.

1. *Original Appalachian* Applies Here

There can be no reasonable dispute that *Original Appalachian* applies here. This Court has repeatedly found—and the Second Circuit has affirmed—that *Original Appalachian* provides the relevant framework for evaluating consumer confusion, and that finding should not be disturbed, particularly here in the context of a motion to dismiss. *See Naser Jewelers, Inc. v. City of Concord*, 538 F.3d 17, 20 (1st Cir. 2008) (holding that law-of-the-case doctrine applies to findings from a preliminary injunction motion when the record was "sufficiently developed and facts necessary to shape the proper legal matrix we[re] sufficiently clear."); *see also Arizona v. California*, 460 U.S. 605, 618 (1983) (The law-of-the-case "doctrine posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.").

Ignoring the language of the Lanham Act and *Original Appalachian*'s caselaw progeny, the Online Defendants argue that *Original Appalachian* should be limited to its facts, such that it only applies where there is a licensing agreement prohibiting the sale of products outside the licensed territory. Defs. Br. at 15-16. They then seek to impose this limitation on Abbott by

requiring that it specifically plead that it prohibited its foreign consignees from selling international FreeStyle test strips in the United States. The Online Defendants overreach.

The restriction the Online Defendants seek to impose finds no support in the Lanham Act. The Lanham Act prohibits parties from using an infringing mark "without the consent of the registrant." 15 U.S.C. § 1114(1). Nor does *Original Appalachian* require that the registrant enter into an agreement explicitly prohibiting the unlawful diversion of its goods. The test set forth in *Original Appalachian* is that a likelihood of confusion exists if the gray goods "were not intended to be sold in the United States and, most importantly, were materially different from" the domestic goods. 816 F.2d at 73. For the first part of this test, Abbott alleges that international FreeStyle test strips, as packaged, are not intended for sale and are in fact prohibited from sale in the United States. SAC ¶¶ 3-4, 11-13, 353-354, 379.

The artificial restriction Defendants seek to impose not only finds no support in the statute or caselaw, but was essentially rejected by the *Original Appalachian* Court. While the plaintiff Original Appalachian Artwork's licensing agreement prohibited the defendant Granada Electronics from diverting the licensed product, there was also evidence that Original Appalachian consented to the importation of the infringing goods by listing Granada on the application for trademark recordation with the U.S. Customs Service. The Court rejected that argument, finding that this did "not extinguish [plaintiff's] rights to claim infringement or seek exclusion … in a private suit in federal court." 816 F.3d at 73. Certainly, if a registrant can maintain a claim for infringement despite expressly identifying the defendant as an authorized importer, then the existence of an agreement expressly prohibiting infringement is not required.

Again, the question is whether Abbott authorized or consented to the Defendants' diversion of international FreeStyle test strips. It has not. Abbott and federal authorities have

not approved international strips for sale in the United States, and when Abbott discovers FreeStyle test strips that are not suitable or approved for sale in the United States, it acts with the authorities to remove those strips from the domestic market. SAC ¶ 379. There is no evidence and no allegations in the Complaint that Abbott has authorized any entity, including the Online Defendants, to sell international FreeStyle test strips in the United States. Accordingly, the Online Defendants' attempt to distinguish or otherwise restrict *Original Appalachian* fails.

2. The Online Defendants Are Liable for Their Sales to Distributor Customers and End-User Customers

The Online Defendants argue that there is no likelihood of confusion because their customers have a different set of expectations. According to Defendants, *all* online customers are end-users that are "more price conscious and discerning," know exactly what they are getting, and "disregard the packaging" of FreeStyle test strips. Defs. Br. at 3. The premise of this argument is contradicted by both the Complaint and the record, and the conclusions the Online Defendants wish to draw therefrom have no basis in fact or reason.

The Online Defendants' entire argument rests on a flawed portrayal of the online market. They did not sell international FreeStyle test strips only to end-users. Rather, they sold to all types of customers, including fellow gray-market diverters. In other words, they acted as both wholesalers and retailers. The only difference is that the Online Defendants often had no idea who their customers were. If they did, they likely would not have sold to Abbott. SAC ¶¶ 486-87, 493. They did not know they were selling to Abbott, what Abbott expected to receive, and what Abbott intended to do with the product. The very fact that they sold diverted international FreeStyle strips to Abbott shows that not all of their customers are end-users. In addition to selling to Abbott, the Online Defendants own production demonstrates that they sold to other diverters. For instance, documents produced *by the Online Defendants* show that movant

MISAR sold international FreeStyle test strips to movant NWHOLESALEDEALS.[1] As to the remainder of their customers, the Complaint does not allege that they are end-users and Defendants cannot demonstrate as a matter of law that they were.

Because the Online Defendants sold to other diverters, they are "liable for not just point-of-sale confusion, but for post-sale confusion as well." D.E. # 131 at 10; *see, e.g., Au-Tomotive Gold Inc. v. Volkswagen of Am., Inc.*, 603 F.3d 1133, 1136-37 (9th Cir. 2010) (noting that "[a]pplication of the 'first sale' doctrine has generally focused on the *likelihood of confusion among consumers*," but holding that relevant confusion also encompasses "post-purchase confusion, even among non-purchasers") (emphasis added); *Gen. Motors Corp. v. Keystone Auto. Indus., Inc.*, 453 F.3d 351, 358 (6th Cir. 2006) (holding that even where retailers are not confused by product, distributor may be nevertheless be liable for confusion among "subsequent purchasers"); *Nitro Leisure Prods., LLC v. Acushnet Co.*, 341 F.3d 1356, 1363 (Fed. Cir. 2003) (examining consumer confusion, not retailer confusion, in applying the "material difference" test).

3. The Differences Between U.S. and International FreeStyle Test Strips Are Material to Online Consumers

Even if it were somehow possible to conclude as a matter of law that all of the Online Defendants' customers were end-users (it is not), there is no basis to treat them as a different species of consumer. The Online Defendants' entire argument relies on the sole fact that their customers purchased international FreeStyle test strips online. The Online Defendants would have the Court draw all types of inferences from this lone fact, including that these customers are more price conscious, are more discerning, read all of the consumer feedback and reviews, and

[1] This information is not part of the pleadings and there is therefore no reason to submit it at this stage.

are only "after the strips and will disregard the packaging." No such inferences can be drawn, particularly at this stage where all inferences are drawn in Abbott's favor.

As an initial matter, the customer feedback the Online Defendants seek to rely on was not attached to the Complaint, was not referenced in the Complaint, and is therefore extrinsic to the pleadings. *See Subaru Distribs.*, 425 F.3d at 122. There has never been a better reason why such materials may not be considered in evaluating the facial plausibility of the Complaint. They are anonymous reviews that are being introduced first as pure hearsay to prove that the reviewing customers were in fact diabetic consumers who did not have insurance and that they "were satisfied with the purchase in every way." Defs. Br. at 4. Second, without any foundation beyond the say-so of counsel, the Defendants seek to introduce this feedback as proof that other customers saw the feedback and were "informed about product they were purchasing." *Id.* The Online Defendants' proffer and use of these materials is incredible.

Turning back to the actual Complaint, Abbott has carefully alleged the numerous material differences between U.S. and international FreeStyle test strips. *See* SAC ¶¶ 11-13, 353-67. The Online Defendants admit as much: "Abbott makes copious and detailed allegations of differences in packaging." Defs. Br. at 15. The Court has found that these differences exist and are material. D.E. # 131 at 2-5, 11-12. Neither the Complaint nor the Court's rulings draw any distinction between consumers who buy test strips in person, by mail, or online. While online consumers might not be in a position to use insurance for their purchases, their status as uninsured consumers does not make the differences between domestic and international strips any less material.

As alleged in the Complaint, all consumers would be confused if they received a box of strips that: instructed them they could test a wider range of sites than what their doctor informed

them[2] and what the FDA has approved (SAC ¶ ¶ 356-57); did not have the U.S. toll-free phone number (SAC ¶ 358); contained instructions that were not in English, or were in other languages that they had never seen before (SAC ¶¶ 359-360); had symbols that they did not understand (SAC ¶¶ 361-63); utilized different units of measurement (SAC ¶¶ 364-65); and were missing critical warnings (SAC ¶ 366). That some consumers may be uninsured and paying out of pocket is irrelevant to materiality.

Given the allegations in the Complaint, the Online Defendants can only resort to sophistry and skepticism. *See, e.g.*, Defs. Br. at 9 ("Moving Defendants are deeply skeptical of Abbott's claims that the differences in packaging are material."). They claim, without any factual support, that uninsured online consumers are more "discerning when making a purchase." Defs. Br. at 3. Discerning of what? The fact that they are looking for a better price does not

[2] The Online Defendants attempt—somewhat comically—to rely on Abbott's website to create a factual dispute concerning the instructions. First, they claim that Abbott's own website "is not country-specific." Defs. Br. at 9 (citing Gangat Decl, Ex. I). This is false. The Online Defendants fail to understand that the website they accessed is the U.S.-specific site. *See* https://www.myfreestyle.com/. By accessing the website from the United States, their web browser is customized to that locality. If this was not clear, the same website's Online Terms and Conditions make it clear. *See* http://www.abbott.com/online-terms-and-conditions.html ("This Policy applies to residents of the United States."). While Defendants could access other country-specific websites, such as Abbott's United Kingdom website, they will receive a pop-up notification that the content on that site "is intended for a UK audience." *See* https://freestylediabetes.co.uk/.

Second, Defendants claim that Abbott's U.S. website provides instructions that conflict with the U.S. package instructional inserts. Defs. Br. at 10. Again, this is false. They rely on a webpage that provides introductory information to potential consumers. *See* https://www.myfreestyle.com/diabetes101-testing. This webpage specifically states that "The information provided is not intended to be used for medical diagnosis or treatment or as a substitute for professional medical advice." If the Online Defendants were not simply trying to muddy the waters, they would have directed the Court's attention to the Virtual Product Manual for FreeStyle Lite, which, among many important things, directs the consumer to "Please read the FreeStyle Lite® test strip package insert for more information." https://www.myfreestyle.com/vpm/FreestyleLite/en/#p=22.

distinguish them from any other purchaser, distributors and end-users alike.[3] There is no basis to conclude that they are looking for a product that is not approved for use in the United States. There is no basis to conclude that they can discern all the material differences simply by reading the anonymous customer feedback or by looking at the stock photos posted by the Defendants. Defs. Br. at 3, 22. And there is no basis to conclude that these consumers will "disregard" or "discard" the packaging and instructions once they receive their purchase. Defs. Br. at 3, 11.

In the end, the Online Defendants all but concede that their arguments are ill-advised at this stage. In support of their argument that the differences are not material to online consumers, the Online Defendants only cite two cases postured on a motion to dismiss. *See* Defs. Br. at 16-20. Both cases strongly favor denial of the motion to dismiss. The Sixth Circuit's ruling in *Brilliance Audio, Inc. v. Haights Cross Commc'ns, Inc.* is particularly compelling. The Circuit reversed the trial court's Rule 12(b)(6) dismissal of plaintiff's Lanham Act claim, finding that "an allegation of a material difference cannot properly be dismissed on 12(b)(6) grounds." 474 F.3d 365, 370 (6th Cir. 2007).

Dial Corp. v. Encina Corp. further counsels against dismissal. There, the district court denied the defendants' motion to dismiss the plaintiff's Lanham Act claims where the plaintiff alleged that the foreign version of its product—soap manufactured for sale in Cyprus—was materially different because it was "made without the active ingredient which consumers have

[3] Furthermore, the Online Defendants' contention that the preliminary injunction hampers uninsured low-income consumers' access to test strips is both irrelevant and false. *See* Defs. Br. at 6-7. Defendants themselves proffer evidence showing a wide selection of test strips offered for sale on Walmart's website. *See* Gangat Decl., Ex. F. Among these offerings are very low-cost "generic" products. For example, a 50-count box of ReliOn Prime Blood Glucose Test Strips sells for $9.00, which is a fraction of the price at which the Defendants sell diverted international FreeStyle test strips. Thus, a price-conscious consumer has much better alternatives than buying unlawfully diverted strips from sources like the Defendants.

come to rely on when using" the American version of the soap. 643 F. Supp. 951, 955 (S.D. Fla. 1986). Defendants' attempt to distinguish between *Dial*, where the soap itself was different, and here, where the packaging and instructions—no doubt part of the product—are different, is meaningless.

4. The Online Defendants' Alleged "Disclaimers" Are Inadequate as a Matter of Law

The Online Defendants also claim that their customers cannot be confused about the materially different FreeStyle test strips because their online listings include a disclaimer that the country of manufacture is not the United States and that "Packaging May Vary." Defs. Br. at 21. As with the customer feedback, the online listings on which the Online Defendants' rely are not part of the Complaint and therefore may not be considered in ruling on the sufficiency of Abbott's pleadings. These listings were submitted in support of Abbott's motion for a preliminary injunction, *see* D.E. # 312, and therefore are extraneous to the pleadings, *Cortec Indus.*, 949 F.2d at 47.

Even if this evidence was properly before the Court on this motion, the Online Defendants do not acknowledge, let alone meet, the stringent test for *proving* that its disclaimers are sufficient to avoid all consumer confusion by warning all consumers of the differences between U.S. and international FreeStyle test strips.

In *Home Box Office, Inc. v. Showtime/The Movie Channel, Inc.*, 832 F.2d 1311 (2d Cir. 1987), this Court summarized and credited the extensive literature that concludes "disclaimers are frequently not effective" in reducing confusion. *Id.* at 1316; *see also Charles of the Ritz Grp. Ltd. v. Quality King Distribs., Inc.*, 832 F.2d 1317, 1324 (2d Cir. 1987) (same). This Court concluded that there is "a *heavy burden* on [the defendant] to come forward with evidence sufficient to demonstrate that any proposed [disclaimer] would *significantly reduce* the

likelihood of consumer confusion." *Home Box Office*, 832 F.2d at 1316 (emphasis added). In placing this affirmative burden on defendants, this Court noted that "this assignment of the burden of proof ... might make it significantly more difficult" for defendants to escape liability on the basis of a disclaimer, but held the burden was appropriately placed on the alleged infringer. *Id.*

The effectiveness of a disclaimer requires a fact-intensive evaluation, such that "no disclaimer should issue without a full hearing regarding its likely effectiveness." *Id.* The only case Defendants can identify where a disclaimer was considered on a motion to dismiss is *Technomarine SA v. Jacob Time, Inc.*, 905 F. Supp. 2d 482 (S.D.N.Y. 2012). In *Technomarine*, the Court rejected the plaintiff's "allegations supporting a *Polaroid*-styled likelihood of consumer confusion," finding that the defendant Jacob Time's website disclaimer "explain[ing] it is not an authorized TechnoMarine seller" removed any chance of actual confusion under the fifth *Polaroid* factor. *Id.* at 489. The confusion the *Technomarine* Court was concerned with was confusion as to the source of the product (watches) and whether a consumer could reasonably believe that Jacob Time was an authorized seller of TechnoMarine's watches in light of the disclaimer.

Setting aside the *Technomarine* Court's unexplained shifting of the burden of proof to the plaintiff, *Technomarine* is legally and factually inapposite to this case. As explained above, the consumer confusion caused by the Online Defendants' diversion of international FreeStyle test strips must be evaluated under *Original Appalachian* and not *Polaroid*. Factually, Jacob Time's disclaimer addressed the very type of confusion at issue there, namely the potential that consumers will associate the defendant with the plaintiff. The same goes for the Online Defendants' other cases. *See, e.g.*, *Home Box Office*, 832 F.2d at 1315 (remanding for further

proceedings concerning the defendant's disclaimer of any link between HBO and Showtime); *Heraeus Kulzer LLC v. Omni Dental Supply*, 2013 U.S. Dist. LEXIS 91949, at *19 (D. Mass. July 1, 2013) (finding a question of fact as to how many customers would actually view the website disclaimer that defendant "is not affiliated with or an authorized dealer of any dental manufacturer"); *cf. VAS Indus., Inc. v. New York Sound, LLC*, 2006 U.S. Dist. LEXIS 41427, at *9 (S.D.N.Y. June 21, 2006) (granting preliminary injunction and finding irreparable harm where "the undercutting of plaintiff's prices and the failure to notify consumers of the difference in the voltage could damage plaintiff's reputation for selling high quality goods and threaten plaintiff with a loss of both sales and prestige").

The Online Defendants' alleged disclaimers, on the other hand, cannot even begin to address the type and extent of confusion caused by the differences between U.S. and international FreeStyle test strips. Defendants' first "disclaimer" is no disclaimer at all. All FreeStyle test strips are manufactured outside the United States in Ireland. SAC ¶ 375. That certain of Defendants' online listings state that "the country of manufacture was a country other than the United States" (Defs. Br. at 22) simply confirms this and disclaims nothing. What is unsettling is that in some instances the Online Defendants' listings create more confusion by actually misrepresenting the country of manufacture as Austria. *See* Decl. of Mohammed Gangat, Ex. A at 37. The Online Defendants' motion glosses over this fact.

The Online Defendants' inclusion of the phrase "Packaging May Vary" fares no better. On its face, this boilerplate statement provides zero information concerning how the product varies, what it varies from, or whether the variations are cleared by the FDA. The conditional term "may" introduces further uncertainty. The record is devoid of any information concerning the effectiveness of this language, let alone that it "fully inform[s]" consumers. Defs. Br. at 3.

There is nothing in the Complaint or the record concerning how a customer would have understood this "variation" language. *See Heraeus Kulzer*, 2013 U.S. Dist. LEXIS 91949, at *20 (finding a dispute of fact as to how many customers actually view the disclaimer and how they would understand it). In lieu of any actual evidence concerning the effectiveness of this language, the Online Defendants contend that customers must have seen the language given its location in the listing. Yet there is no evidence that any customers did. And if they did see it, the Online Defendants can only offer speculation about what their customers might or might not have expected. This is not evidence, and is certainly not enough to warrant dismissal as a matter of law.

As to the other gray-market distributors that they also sold to, the Online Defendants made no disclaimers to the actual consumers, and took no other measures to prevent consumer, as opposed to retailer, confusion. The Online Defendants' supposed disclaimers do not appear on the product itself and are not passed on to the purchasing consumer. Furthermore, there is no evidence that the Online Defendants made any effort to encourage their customers (other distributors) to make similar disclosures to the consuming public. As courts have recognized—and as common sense dictates—disclaimers made only to the direct customer, not visible on the product itself, can have no effect on downstream confusion. *See, e.g., Au-Tomotive Gold v. Volkswagen of Am.*, 457 F.3d 1062, 1077 (9th Cir. 2006) (collecting cases); 4 McCarthy on Trademarks and Unfair Competition § 23:7 (4th ed.); *see also United States v. Torkington*, 812 F.2d 1347, 1353 (11th Cir. 1987) (the confusion contemplated by the Trademark Counterfeiting Act—the relevant language of which is identical to the Lanham Act—includes confusion to potential purchasers in the public who may not have the ability or opportunity to view disclaimers on display for only direct purchases).

In sum, the Online Defendants have not carried the "heavy burden" of proving their asserted disclaimer would mitigate the materiality of the differences and the consequent confusion they cause to both their immediate customers and end-user consumers.

B. The Online Defendants' Sale of International FreeStyle Test Strips Undermines Abbott's Quality-Control Measures

The Online Defendants' sale of international FreeStyle test strips undermines Abbott's quality control, which constitutes a second, alternative basis for Lanham Act liability. The Online Defendants argue, however, that Abbott does not articulate why its recalls are country-specific and that their diversion of FreeStyle test strips at worst makes it "more difficult" to execute a recall. Defs. Br. at 24-25. This argument ignores both Abbott's actual allegations and common sense.

"One of the most valuable and important protections afforded by the Lanham Act is the right to control the quality of the goods manufactured and sold under the holder's trademark." *El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392, 395 (2d Cir. 1986). A defendant who interferes with a trademark owner's quality-control measures "subjects the trademark holder to the risk of injury to the reputation of its mark." *Zino Davidoff SA v. CVS Corp.*, 571 F.3d 238, 243 (2d Cir. 2009). A diverted good that does not meet the trademark owner's quality-control standards "is deemed for Lanham Act purposes not to be the genuine product of the holder, and its distribution constitutes trademark infringement." *Warner-Lambert Co.*, 86 F.3d at 6.

The sale of international FreeStyle test strips in the United States interferes with Abbott's long-established quality-control measures. Contrary to the Online Defendants' contention, Abbott has not invoked its quality-control measures as a mere "talisman" or "utterance." Defs. Br. at 24. Abbott's allegations clearly establish that its quality-control measures are "legitimate, established, substantial, and nonpretextual." *Warner-Lambert Co.*, 86 F.3d at 6. FreeStyle test

strips are manufactured with a specific lot number. *See* SAC ¶ 375. Each lot is manufactured for sale in a specific country or region. *Id.* Prior to distribution, Abbott ensures that its FreeStyle test strips are packaged with labels and instructions that are approved for sale by the regulatory requirements of the intended country of distribution. *See* SAC ¶¶ 11-13, 354-367. The contents of these labels, in particular the toll-free phone number and lot number, allow Abbott to track where test strips are shipped and monitor them if any safety or quality issue arises. *Id.* ¶ 376. Abbott then takes great care to ensure that FreeStyle test strips are shipped under conditions designed to maintain their safety and integrity. *Id.* ¶ 14. In the event a safety or quality issue arises after distribution, Abbott has rigorous protocols in place to address any such issues. *Id.* ¶¶ 377-80.

The Online Defendants' invocation of *Polymer* is erroneous. In *Polymer*, the court was engaged in factfinding for purposes of ruling on a motion for a preliminary injunction.[4] It denied the motion, finding that Polymer "did not carefully police any procedures it may have had in place to ensure that the necessary information appeared on [its] packaging" and had "no procedures in place to prevent its non-sealed kits from reaching the retail public." 37 F.3d at 79. Here, Abbott has alleged that it "devotes a substantial amount of effort and resources to ensure product quality and consumer safety." SAC ¶ 379. These efforts and resources are expended through the entire life of the product. And unlike *Polymer*, this Court actually found that Abbott

[4] In fact, none of the cases on which the Online Defendants rely are procedurally apposite—clearly a theme that runs throughout their papers. *See PepsiCo, Inc. v. F & H Kosher Supermarket Inc.*, 2011 U.S. Dist. LEXIS 143331 (E.D.N.Y. Aug. 26, 2011) (default judgment); *Dan-Foam A/S v. Brand Named Beds, LLC*, 500 F. Supp. 2d 296 (S.D.N.Y. 2007) (summary judgment); *Shell Oil Co. v. Commercial Petroleum, Inc.*, 928 F.2d 104 (4th Cir. 1991) (trial); *Adolph Coors Co. v. A. Genderson & Sons, Inc.*, 486 F. Supp. 131 (D. Colo. 1980) (permanent injunction).

"has in place and abides by established, legitimate, substantial, and nonpretextual quality-control measures." D.E. # 131 at 14.

The Online Defendants are left with attorney argument that product recalls need not be country-specific, that regulators are not essential to the recall process, and that Abbott should be able to trace its product throughout the world regardless of where it is diverted to. Abbott has pleaded, and the Court has found,[5] that targeted country-specific recalls are more efficient, more effective, and less disruptive than market-wide recalls. *See* SAC ¶¶ 377-78; D.E. # 131 at 13-14. Abbott has alleged that it engages the relevant regulatory agencies throughout the recall process. SAC ¶ 377. And of course, Abbott alleges that it manufactures and distributes each lot for a specific country or region, and can only track those lots if they remain in their intended country. SAC ¶ 378. Notwithstanding these allegations, the Online Defendants state that "Abbott's allegations fail to establish that tracking lot numbers is only possible if the lots are confined to specific countries." Defs. Br. at 25. This statement strains credulity. Lot numbers enable Abbott to identify the affected countries, provide notification to the affected distributors, retailers, pharmacies, and where possible consumers and health care professionals, and take any other steps necessary to a recall or other field action. SAC ¶¶ 377-79.

The Online Defendants' complete lack of understanding of this process and the important actions Abbott must take is revelatory and troublingly so. In *F&H Kosher Supermarket*, the court found infringement under the quality-control test where diversion of Israeli Pepsi prevented plaintiff from "rotating stale, damaged or substandard quality" soda off retail shelves. 2011 U.S.

[5] The HMF Defendants raised a similar challenge to Abbott's allegations that issuing worldwide recall notices would reduce their overall efficacy. This Court rejected that challenge, finding that their "skepticism alone is not enough to call into question Abbott's reasonable, sworn-to assertion, particularly since cases have recognized the legitimate value in targeted rather than marketwide recalls." D.E. # 258 at 11 (citing *Zino Davidoff*, 571 F.3d at 243-45).

Dist. LEXIS 143331 at *12. If product diversion that subverts Pepsi's efforts to keep flat soda off of retail shelves constitutes infringement, so too does diversion that potentially exposes U.S. consumers to recalled medical devices.

By diverting test strips out of their intended market, the Online Defendants undermined Abbott's efforts to address product defects with effective recalls that are "small and targeted," *see Zino Davidoff*, 571 F.3d at 244-45; they also prevented U.S. consumers from being able to call the U.S. toll-free phone number with any inquiries, complaints, or issues, *see* SAC ¶¶ 12, 358. Their acts thus constitute trademark infringement. *See Zino Davidoff*, 571 F.3d at 244-45; *see also Bel Canto Design, Ltd. v. MSS HiFi, Inc.*, 837 F. Supp. 2d 208, 232 (S.D.N.Y. 2011) (finding that alteration of serial numbers thwarted trademark holder's efforts to make a "targeted recall" and constituted trademark infringement).

III. THE COMPLAINT STATES A PLAUSIBLE CLAIM FOR IMPORTATION OF INFRINGING GOODS

Many of the defendants already moved to dismiss Abbott's claim for importation of infringing goods on the mistaken basis that the importation of international FreeStyle test strips is not infringing because they do not contain a counterfeit or spurious mark. While the Online Defendants seek to join in those motions (*see* Opening Br. at 2), they nonetheless reargue this point in their brief. *See* Opening Br. at 28. As the Online Defendants' argument is nearly verbatim of that of the other defendants, Abbott refers the Court to Plaintiffs' Omnibus Memorandum of Law in Opposition to Defendants' Motions to Dismiss, D.E. # 675 at 21-23.

IV. THE REMAINDER OF THE ONLINE DEFENDANTS' MOTION SHOULD BE DENIED

The Online Defendants' arguments for dismissal of Abbott's claims for trademark dilution, deceptive business practices, and contributory trademark infringement are entirely dependent on dismissal of Abbott's trademark infringement claims. Because the Online

Defendants' motion to dismiss Abbott's trademark infringement claims fails, so too must their motion to dismiss Abbott's trademark dilution, deceptive business practices, and contributory trademark infringement claims.

As to Abbott's federal and state law claims for trademark dilution, the Online Defendants sold diverted international FreeStyle test strips and thereby caused Abbott's distinctive trademarks to be associated with a mislabeled product that is likely to confuse consumers and which fails to give them the instructions and customer support to which FreeStyle users are accustomed. SAC ¶¶ 582-91. They therefore diluted Abbott's marks through tarnishment. *See F&H Kosher Supermarket*, 2011 U.S. Dist. LEXIS 143331, at *18 (finding dilution based on sale of diverted soda); *Perkins School for the Blind v. Maxi-Aids, Inc.*, 274 F. Supp. 2d 319, 326 (E.D.N.Y. 2003) (finding claim for dilution adequately pled where plaintiff alleged that defendants sold diverted international product with inferior warranty)

As to Abbott's state law claim for deceptive business practices, the Online Defendants rely on a summary judgment opinion to attempt to restrict the type of injury that is redressable by New York General Business Law. *See* Defs. Br. at 27 (citing *Zip Int'l Grp., LLC v. Trilini Imports*, 2011 U.S. Dist. LEXIS 55270, at *28 (E.D.N.Y. May 24, 2011)). In any event, Abbott's state law deceptive business practices claim is more than adequately pled. Abbott has alleged that the Online Defendants' deceptive acts—namely, the selling of mislabeled test strips—were directed at consumers and that this resulted in consumer confusion, as well as harm to the public interest. *See Gucci Am., Inc. v. Duty Free Apparel, Ltd.*, 277 F. Supp. 2d 269, 273 (S.D.N.Y. 2003).

As to Abbott's claim for contributory trademark infringement, Abbott has alleged that the Online Defendants sold diverted international FreeStyle test strips knowing and having reason to

know that their customers would sell those infringing strips to consumers. SAC ¶¶ 486-87, 493, 642. They are therefore both directly responsible and "contributorially responsible for any harm done as a result" of those sales. *Inwood Labs. v. Ives Labs.*, 456 U.S. 844, 854 (1982).

CONCLUSION

For the above reasons, the Online Defendants' motion to dismiss should be denied. Abbott has more than adequately pled that the Online Defendants engaged in trademark infringement. The Online Defendants may dispute Abbott's allegations, but this is not the stage at which to resolve such disputes.

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Respectfully submitted,
PATTERSON BELKNAP WEBB & TYLER LLP

By: _____

Geoffrey Potter
gpotter@pbwt.com
Aron Fischer
afischer@pbwt.com
Timothy A. Waters
twaters@pbwt.com
R. James Madigan III
jmadigan@pbwt.com
Matthew Funk
mfunk@pbwt.com

1133 Avenue of the Americas
New York, NY 10036-6710
Tel: (212) 336-2000
Fax: (212) 336-2222

Attorneys for Plaintiffs Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corporation